31. (New) An apparatus for dispensing a medicament, wherein at least a portion of one or more internal surfaces of the apparatus that come into contact with medicament during storage or dispensing has a layer of one or more cold plasma polymerised monomers bonded to at least a portion thereof, wherein the apparatus does not include a pressurised container of the medicament and wherein the layer is not of a cold plasma polymerised fluorinated hydrocarbon.

REMARKS

Following amendment of the present application, new claims 15-31 are presented for examination. Of these claims, claims 15, 17, and 31 are independent.

Each of these independent claims recites "an apparatus for dispensing a medicament, wherein at least a portion of one or more internal surfaces of the apparatus that come into contact with medicament during storage or dispensing has a layer of one or more cold plasma polymerised monomers bonded to at least a portion thereof." Claim 15 further recites that "the apparatus is not a pressurised container of the medicament or a metering valve for a pressurized container"; claim 17 further recites that "the layer is not of a cold plasma polymerised fluorinated hydrocarbon"; and claim 31 further includes each additional recitation of claims 15 and 17.

Support for the invention of claim 15 and 31 can be found in the application as filed at, for example: page 1, lines 27-31 ("Other drug delivery devices include apparatus in which capsules containing a powdered medicament are mechanically opened at a dispensing station where inhaled air subsequently entrains the powder, which is then dispensed through a mouthpiece."); page 8, lines 5-9 ("In a typical dry powder inhaler, the inner surface of the mouthpiece may be treated as well as any channel leading to the mouthpiece from the point of powder storage, i.e., from a capsule, bulk storage chamber of a pre-metered chamber of a device."); and page 8, lines 30-34 ("The method can also be used to treat components of many other delivery devices including nasal pumps, non-pressurised actuators, foil storage types, breath actuated inhaler devices and breath coordinating devices and so on."). Support for the invention of claims 17 and 31 can be found in the application as filed at, for example: page 6, line 28-page 7, line 2 ("cold plasma polymerisation treatment of one or more monomers"); and page 7, lines 14-16 ("Siloxanes, such as dimethyl siloxane, may be used...to give a layer of plasma polymerised dimethylsiloxane.").

Regarding the amendments to the specification, both the paragraph beginning on page 2, line 31 and ending on page 3, line 3, and the paragraph beginning on page 7, line 3 and ending on page 7, line 16, have been amended to conform these two paragraphs to the corresponding paragraphs in the grandparent international patent application. Applicant notes that the grandparent international patent application has been incorporated by reference into the present application as well as in the parent application. Both the paragraphs beginning on page 5, line 35

and ending on page 6, line 10, and the paragraph beginning on page 7, line 35 and ending on page 8, line 34, have been amended to correct obvious typographical errors. In the first paragraph, reference number 124 is changed to reference number 123 and in the second paragraph, the incomplete sentence has been corrected by adding the implied verb. Finally, a new paragraph has been added to emphasize the embodiments of the invention recited in independent claims 15, 17, and 31.

It is the position of Applicant that the presentation of these new claims in this continuation application presents no bar to the application of the doctrine of equivalents and that no equivalents are surrendered. The new claims simply reflect varying new scopes of patent protection that are now sought. Applicant notes, for example, that new claims 15 and 17 each exceeds the scope of original claim 1, while new claim 31 substantially corresponds to the scope of original claim 1.

Regarding the outstanding Official Action in the parent application, to which no response was submitted and the application was subsequently abandoned, Applicant notes that the primary reference relied upon for the rejection of each claim is Ashurst et al., WO 96/32345 ("*Ashurst*"). Specifically, *Ashurst* is cited in the Official Action as disclosing "an apparatus for dispensing a medicament, wherein at least a portion of one or more of the internal surfaces of components of the apparatus which come into contact with the medicament during storage or dispensing has a layer of one or more cold plasma polymerised monomers bonded to at least a portion thereof and where the apparatus is a pressurised dispensing container."

In contrast, Applicant respectfully submits that *Ashurst* fails to disclose, *inter alia*, a layer of one or more cold plasma polymerised monomers as recited in the present claims and described on page 7, lines 17-34, of the application. In *Ashurst* a fluoro carbon polymer generally is applied to an internal surface of a metered dose inhaler in a two-step process comprising a first coating step followed by a curing step. *See, e.g., Ashurst*, page 5, line 33-page 6, line 7; page 7, lines 9-10; page 8, lines 31-page 10, line 2; examples 1-4, 6-9, 11-14, and 16-17. In the other examples, the MDI cans are spray-coated with a FEP powder using an electrostatic gun. *See* examples 5, 10, and 15. Nowhere does *Ashurst* disclose or teach the application of a polymer film by cold plasma polymerisation of monomers.

Indeed, the teaching of *Ashurst* is away from cold plasma polymerisation, as most of the examples of Ashurst involve a curing step at high temperatures following a coating step as part of the overall process. *See* Examples 1-4, 6-9, 11-14, and 16-17. With regard to using plasma polymerisation to form the coating, *Ashurst* discloses that the fluorocarbon polymer/polymer blend is formed *in situ* of the can walls using plasma polymerisation of fluorocarbon monomers (page 9, lines 17-18). The curing step is discussed further on page 9, lines 22-31, where it is stated that, for plasma polymerisation, the curing step is carried out at temperatures of from 20° Celsius to 100° Celsius.

In view of the disclosure of *Ashurst*, Applicant submits that this reference fails to disclose or suggest an apparatus having one or more fluorinated internal surfaces *wherein the coating step is carried out using cold plasma polymerisation of monomers such that internal surfaces of the apparatus have a layer of cold plasma polymerised monomers*.

In view of the foregoing, Applicant submits that claims 15-31 presented for examination in the present application stand in condition for allowance, and Applicant respectfully requests the passing of the present application to issue.

Respectfully submitted,

Chad D. Tillman

Chad D. Tillman
U.S. Reg. No. 38,634
MORRIS MANNING & MARTIN, L.L.P.
Suite 1125
6000 Fairview Rd.
Charlotte, NC 28210
(704) 554-5032

AMENDMENTS TO THE SPECIFICATION

According to the invention, there is provided apparatus for dispensing a medicament, wherein at least a portion of one or more of the internal surfaces of components of the apparatus which come into contact with medicament during storage or dispensing has a layer of one or more cold plasma polymerized monomers bonded to at least a portion thereof; with the proviso that the layer is not of a cold plasma polymerized fluorinated hydrocarbon where the apparatus is a pressurized dispensing container.

....

Upon depression of the valve stem 111 relative to the valve member 112 so that it moves inwardly into the container, the radial port 123[124] is closed off as it passes through the inner seal 118, thereby isolating the metering chamber 113 from the contents of the pressurized container. Upon further movement of the valve stem 111 in the same direction to a dispensing position the discharge port 121 passes through the outer seal 117 into communication with the metering chamber 113. In this dispensing position the product in the metering chamber 113 is free to be discharged to the atmosphere via the discharge port 121 and the cavity in the hollow end 119 of the valve stem 111.

....

The preferred monomers to use in this process [where the apparatus is not a pressurized dispensing container] are perfluoro-cyclohexane or perfluoro-hexane, which would create a thin layer of plasma polymerized fluoro-cyclohexane or fluoro-hexane on the appropriate surface. Other fluorinated hydrocarbons may also be used, such as tetrafluoroethylene (TFE), trifluoroethylene, vinylidene fluoride and vinyl fluoride. The two monomers fluoroethylene and fluoropropylene may also be used to form the copolymer fluorinated ethylene-propylene (FEP). Siloxanes, such as dimethyl siloxane, may be used with all of the above mentioned drug dispensing devices to give a layer of plasma polymerized dimethylsiloxane.

....

Either an entire component within the drug delivery device, or just the surfaces of one or more components which would come into contact with the medicament during actuation, could be treated to provide an improved drug delivery device according to the present invention. In the case of the type of inhalers as shown in Figure 1, surfaces 21, 22 and 23 may be treated. In a typical dry powder inhaler, the inner surface of the mouthpiece ~~may be treated as well as~~ and any channel leading to the mouthpiece from the point of powder storage, i.e., from a capsule, bulk storage chamber or a pre-metered chamber of a device. In the metering valve of Figure 2, the valve member 112 alone may be treated. However, additional benefits can be achieved in treating some or all of the other plastic and rubber parts of the valve, including the valve body 114 and the seals 116, 117 and 118. Treatment of the seals 117 and 118 has the additional benefit that friction between the seals 117 and 118 and valve stem 111 is reduced resulting in easier operations of the device. The level of friction between the valve stem 111 and seals 117 and 118 may be further reduced by treatment of the valve stem 111 itself. Such treatment reduces or eliminates the need for silicone emulsions or oils to be applied to the seals 117 and 118 and valve stem 111. Treatment of the seals 116, 117 and 118 also has the benefits of reducing levels of extractibles where the seals are manufactured from elastomeric materials, reducing the permeability of the seals to the propellant in the pressurised dispensing container and reducing the levels of absorption of product onto the surfaces of the seals. The method can also be used to treat components of many other delivery devices including nasal pumps, non-pressurised actuators, foil storage types, breath actuated inhaler devices and breath ~~co~~ ordinating coordinating devices and so on.